Beverly Hills Prosthetics Orthotics, Inc.

SEP 9 2002

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510(k) Number: K022273

510(k) SUMMARY
(as required by section 807.92(c))
CRANIAL SYMMETRY SYSTEM

BEVERLY HILLS PROSTHETICS ORTHOTICS, INC.

This 510(k) summary of safety and effectiveness for the *Cranial Symmetry System* helmet is submitted in accordance with requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Beverly Hills Prosthetics Orthotics, Inc.
Address:	6300 Wilshire Blvd., Suite 150 Los Angeles, CA 90048
Contact Person:	Keith E. Vinnecour, President, C.P.O.
Telephone:	323-866-2555 (telephone) 323-866-2560 (facsimile)
Preparation date:	March 21, 2002
Device Trade Name:	Cranial Symmetry System
Common Name:	Cranial Orthosis
Classification Name:	Cranial Orthosis (see C.F.R. 882.5970)
Product Code:	MVA

510(k) Number: K022273

Predicate Device:	Clarren Helmet, 510(k) number K003035 Beverly Hills Prosthetics Orthotics, Inc. is claiming substantial equivalence with Cranial Symmetry System to the legally marketed device Clarren Helmet (K003035) per 807.92(a)(3).
Device Description:	The *Cranial Symmetry System* provides passive pressure to the prominent areas of the infants' skull while allowing for growth into the flattened areas. There are no exceeding pressures that could put restrictions on brain growth. The cranial orthosis helmet is custom fabricated with lightweight materials. The outer shell consists of a sheet of three-sixteenths inch thick polypropylene. The padded inner liner consists of three-sixteenths inch Aliplast. These materials are vacuumed formed over the modified plaster cast mold of the infants' skull. There is a Velcro chinstrap that is used as a method of suspension. The chinstrap is fastened securely through the Dacron loops at the cut out section for the infants' ears. The chinstrap holds the helmet in place eliminating the risk of slippage. There are air holes drilled into the helmet for ventilation.
Intended Use:	The Cranial Symmetry System is intended for medical purposes to provide contact to prominent areas of the cranium while allowing space for growth in the flattened areas in order to improve cranial symmetry in infants' three to eighteen months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants' with plagiocephalic and brachycephalic shaped heads.

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Indications For Use:

The sale and distribution of the device is restricted to prescription use in accordance with 21CFR801.109

The Cranial Symmetry System is intended for medical purposes to provide contact to prominent areas of the cranium while allowing space for growth in the flattened areas in order to improve cranial symmetry in infants' three to eighteen months of age, with plagiocephalic and brachycephalic shaped heads.

Technological Characteristics Compared to Predicate Device:

The Cranial Symmetry System and the predicate device (The Clarren Helmet) are both classified as cranial orthosis (21CFR882.5970). The Cranial Symmetry System uses a 3/16" thickness polypropylene and the Clarren Helmet uses a 3/8" thickness polypropylene. The padded lining in the Cranial Symmetry System helmet is a 3/16" thickness Aliplast and the Clarren Helmet uses a 1/4" thick Plastizote. Both are closed cell copolymer foams. Both helmets are custom fabricated by vacuum forming the materials over the modified cast mold of the infant's skull. There are cutouts for the ears in bot designs, as well as air holes for ventilation. Helmet therapy was introduced to Beverly Hills Prosthetics Orthotics, Inc. by Sterling Clarren M.D. and therefore the methodology and technique for measurements and casting gleaned is still used in practice today.

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Performance Data:	Clarren, Sterling, M.D., "Plagiocephaly and torticollis: Etiology, natural history, and helmet treatment, *"Journal of Pediatrics,* 98:1 (92-95)(Jan. 1981); Clarren, et al., "Helmet treatment for plagiocephaly and congenital muscular torticollis," *Journal of Pediatrics*, 94:1 (43-46)(Jan. 1979).
Conclusions:	Based on the foregoing and all information included in this 510(k) application, Beverly Hills Prosthetics Orthotics, Inc. believes that the performance data provides reasonable assurance of the safety and effectiveness of the Cranial Symmetry System for its proposed indications for use. Further, the Cranial Symmetry System is substantially equivalent to its claimed predicate device under the conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 2002

Keith E. Vinnecour, President, C.P.O.
Beverly Hills Prosthetics Orthotics, Inc.
6300 Wilshire Blvd., Suite 150
Los Angeles, California 90048

Re: K022273
Trade/Device Name: Cranial Symmetry System
Regulation Number: 21 CFR 890.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: July 11, 2002
Received: July 25, 2002

Dear Mr. Vinnecour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

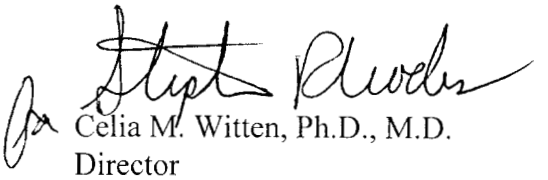
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE OF THE *CRANIAL SYMMETRY SYSTEM* HELMET

The *Cranial Symmetry System* is intended for medical purposes to provide contact to prominent areas of the cranium while allowing space for growth in the flattened areas in order to improve cranial symmetry in infants' 3 to 18 months of age, with plagiocephalic and brachycephalic shaped heads.

The sale and distribution of the device is restricted to prescription use in accordance with 21CFR801.109

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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